health. FDA said that the proposed changes would be an important step toward global harmonization of safety reporting requirements and additional efforts are underway within the Department of Health and Human Services to harmonize the reporting requirements of U.S. Federal agencies (e.g., FDA and the National Institutes of Health are continuing to work together to address the best ways to streamline information sharing and to harmonize, to the extent possible, the safety reporting requirements of the two agencies).

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1587 Filed 2–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0045]

Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing (NAT).'' The purpose of the public workshop is to address regulatory and scientific challenges and opportunities in the development of policy concerning protection of the blood supply from transfusion-transmissible diseases by deferring blood donors based on high-risk behavior, and to request comments on this topic.

Date and Time: The public workshop will be held on March 8, 2006, from 8 a.m. to 5:30 p.m. The deadline for registration via mail, fax, or e-mail is February 17, 2006 (see *Registration*). Written or electronic comments will be accepted until May 8, 2006 (see *Comments*).

Addresses: The public workshop will be held at the National Institutes of Health, Lister Hill Auditorium, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *Rhonda.Dawson@fda.hhs.gov*.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, and telephone and fax numbers) to Rhonda Dawson (see *Contact Person*) by February 17, 2006. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:15 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic comments regarding the public workshop. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the public workshop is to address regulatory and scientific challenges and opportunities in the development of policy concerning protection of the blood supply from transfusion-transmissible diseases by deferring blood donors based on high-risk behavior. The public workshop will feature presentations by national and international experts from government and academic institutions and industry. The following discussions will be included:

- Current practices in the United States and in foreign countries regarding blood donor deferrals based on high-risk behavior,
- Comparison of selected tissue donor deferral policies to blood donor deferral policies,
- Behavioral risks for transfusion-transmitted diseases,
- Residual risks of infection from transfusion, and
- Potential alternative approaches to donor screening and testing.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: January 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1588 Filed 2–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Independent Evaluation of the Food and Drug Administration's First Cycle Review Performance—Retrospective Analysis Final Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Independent Evaluation of FDA's First Cycle Review Performance—Retrospective Analysis Final Report.'' This report describes an independent evaluation of the issues associated with FDA's conduct of first cycle reviews of new molecular entities for new drug applications (NMEs for NDAs), and biological license applications (BLAs). Applications covered by the report are those submitted to FDA in fiscal years 2002 to 2004. This independent study was conducted in relation to the Prescription Drug User Fee Amendments of 2002 (PDUFA III). This assessment includes a detailed evaluation of the events that occurred during the review process with a focus on identifying the best practices by FDA and industry that facilitated that process.

ADDRESSES: Submit written requests for single copies of this report to the Office of Planning (HFP–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic requests to *Carolyn.Staples@fda.hhs.gov*. This

report will be available on FDA's Web site at a later date.

FOR FURTHER INFORMATION CONTACT: Carolyn Staples, Office of Planning (HFP–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5274, or William Hagan, Office of Planning (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8816.

SUPPLEMENTARY INFORMATION:

I. Background

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes PDUFA III. In conjunction with the passage of PDUFA III, FDA agreed to certain performance goals and procedures that were described in an enclosure to a June 4, 2002, letter from the Secretary of Health and Human Services, Tommy Thompson, to Congress entitled ''PDUFA Reauthorization Performance Goals and Procedures'' (PDUFA Goals and Procedures).

One of the goals relates to FDA's performance of first cycle reviews of original NMEs for NDAs and BLAs (PDUFA Goals and Procedures, section 10). Related to this goal, FDA was to retain an independent expert consultant to undertake a study to evaluate issues associated with the agency's conduct of first cycle reviews. The study was to assess the following objectives: (1) Current first cycle review performance and any changes that occur after FDA publishes guidance on Good Review Management Principles (GRMPs), (2) the first cycle review history of all NDAs for new molecular entities and all BLAs during PDUFA III, and (3) the effectiveness of FDA's staff training regarding GRMPs. FDA awarded a contract to an independent expert to study these issues. The report referred to in this document covers the retrospective portion of objectives (1) and (2) listed previously.

In accordance with the PDUFA goal, the report is being made available to the public.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1605 Filed 2–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the SAMHSA Center for Substance Abuse Prevention (CSAP) National Advisory Council on February 14, 2006.

The meeting will be open and will include a Director's Report; discussions related to National Outcome Measures; an update on SAMHSA's Drug Free Communities programs; and a panel presentation on the roles of Project Officers, Grants Management staff and Contracts Management staff.

A roster of Council members may be obtained either by accessing the SAMHSA Council Web site, *http://www.samhsa.gov/council/csap/csapnac.aspx* or by communicating with the contact listed below. Substantive program information, a summary of the meeting, and the transcript for the open session will also be available on the SAMHSA CSAP Council Web site as soon as possible after the meeting. Attendance by the public will be limited to space available.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time: Tuesday, February 14, 2006, 12 p.m. to 5 p.m.

Place: Washington DC Convention Center, 801 Mount Vernon Place, NW., Room 204 B, Washington, DC 20001.

Type: Open.

Contact: Tia Haynes, Committee Management Specialist, 1 Choke Cherry Road, Room 4–1066, Rockville, Maryland 20857. *Telephone:* (240) 276–2436. *Fax:* (240) 276–2430 *E-mail: Tia.haynes@samhsa.hhs.gov.*

Dated: February 1, 2006.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. E6–1623 Filed 2–6–06; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–23795]

Towing Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Towing Safety Advisory Committee (TSAC). TSAC advises the Coast Guard on matters relating to shallow-draft inland and coastal waterway navigation and towing safety.

DATES: Application forms should reach us on or before April 30, 2006.

ADDRESSES: You may request an application form by writing to Commandant (G–PSO–1); U.S. Coast Guard, Room 1210; 2100 Second Street, SW., Washington, DC 20593–0001; by calling 202–267–0214; or by faxing 202–267–4570. Send your original completed and signed application in written form to the above street address. Be sure to sign and include the short page that allows us to keep political affiliation on file. This notice is available on the Internet at *http://dms.dot.gov* in docket USCG–2006–23795 and the application form is also available at *http://www.uscg.mil/hq/g-m/advisory/index.htm.* (Click on ''ACM Application''.)

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Miante; Assistant Executive Director of TSAC, telephone 202–267–0214, fax 202–267–4570, or e-mail *gmiante@comdt.uscg.mil.*

SUPPLEMENTARY INFORMATION: The Towing Safety Advisory Committee (TSAC) is a Federal advisory committee mandated by Congress and operates under 5 U.S.C. App. 2, (Pub. L. 92–463, 86 Stat. 770, as amended). It advises the Secretary of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States in advance of meetings of the International Maritime Organization.

TSAC meets at least once a year at Coast Guard Headquarters, Washington, DC, or another location selected by the Coast Guard. It may also meet for extraordinary purposes. Its working groups may meet to consider specific issues as required. The 16-person membership includes 7 representatives of the Barge and Towing Industry (reflecting a regional geographical balance); 1 member from the Offshore Mineral and Oil Supply Vessel Industry; and 2 members from each of the following areas: Maritime Labor; Shippers (of whom at least one shall be engaged in the shipment of oil or hazardous materials by barge); Port Districts, Authorities, or Terminal Operators; and the General Public.